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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,412	02/13/2004	Guillermo C. Bazan	RUC 86053 UT	7769

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,412	BAZAN ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-24 and 27-33* is/are pending in the application.

4a) Of the above claim(s) *3-5,7,8,10,16,19,20,23,24,29 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,9,12-15,17,18,21,22,27,28 and 30-32* is/are rejected.

7)☒ Claim(s) *1,2,6,12-14,17,27,28 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07 February 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 3-, 7, 8, 10, 16, 19, 20, 23, 24, 29 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 September 2006.

2. For convenience, the traversal presented in the response of 18 September 2006 is reproduced below.

> A requirement for species election was also made for the following claim features should Group I be elected: the multichromophore; the signaling chromophore; the target polynucleotide; and whether the sample comprises single-stranded or double-stranded polynucleotide.
> Applicants elect Group I, claims 1-24 and 27-32. Applicants elect the multichromophore species "conjugated polymer"; to the extent a further election may be required, Applicants elect the structure of claim 9. Applicants elect the signaling chromophore species "fluorescent dye"; to the extent a further election may be required, Applicants elect "fluorescein". Applicants elect the target polynucleotide species "RNA". Applicants elect the sample species as that comprising "single-stranded polynucleotide". Claims reading on the elected species are asserted to be at least claims 1-2, 6, 9, 12-15, 17-18, 21, 22-24, 27-28, and 30-32.

3. As seen above, applicant elected the species of:

   a. The structure of claim 9;

   b. Fluorescein as the signaling chromophore;

   c. The target polynucleotide is RNA and

   d. The sample comprises single stranded polynucleotide.

4. While the response of 18 September 2006 did contain an indication of the clams that read upon the elected invention, said indication included claims 23 and 24, which were held to be withdrawn. Said claims are the focus of the continuing traversal.

5. For convenience, claims 20-24 and 30 are reproduced below.

20. (Withdrawn) The method of claim 1, wherein the target polynucleotide is DNA.

21. (Previously Presented) The method of claim 1, wherein the target polynucleotide is RNA.

22. (Previously Presented) The method of claim 1, wherein the sample comprises single-stranded target polynucleotide.

23. (Withdrawn) The method of claim 1, wherein the sample comprises double-stranded target polynucleotide.

24. (Withdrawn) The method of claim 1, wherein the target polynucleotide is produced via an amplification reaction.

30. (Previously Presented) The method of claim 1, wherein the target polynucleotide is not amplified.

6. It is noted with particularity that applicant had to elect between a sample that comprises single-stranded polynucleotide (claim 22) and a sample that comprises double-stranded polynucleotide (claim 23), and that applicant elected a sample that comprises single-stranded polynucleotide. While claim 24 does not indicate whether or not the amplified oligonucleotide is DNA or RNA, amplification is recognized as producing DNA, not RNA, and as such, claim 24 is drawn to a non-elected invention. In support of this position, attention is directed to the argument presented at page 7 of the response filed 17 May 2007, *infra.*

> Regarding claim 24, amplification does not require that exclusively double-stranded polynucleotides be produced. As the application sets forth at pages 16-19, in particular in the paragraph bridging pages 17-18, a number of amplification methods and strategies are known in the art. Many of these strategies produce an excess of one polynucleotide strand. For example, even PCR when performed with an excess of one amplification primer will produce excess copies of one strand, which copies are necessarily single-stranded. Claim 24 can therefore read on instances in which the target polynucleotide is produced via amplification.

7. The above argument has not been found persuasive for the inclusion of claim 24 in the elected invention for the following reasons. While asymmetric PCR can result in the generation of more of one strand over that of another, the strand so produced is DNA, not RNA. As seem above, applicant specifically elected the species of RNA, in a single-stranded form, as the target polynucleotide, not DNA. Further, in conducting PCR, the sample must comprise double-stranded DNA. As seem above, applicant specifically did NOT elect this species (claim 23). Accordingly, claims 23 and 24 are deemed to be drawn to a non-elected invention.

8. It is noted that the response of 26 November 2007 seeks to introduce new claim 33. Said newly added claim 33 recited that one is to provide "a polycationic multichromophore." Said species was not originally presented, nor elected by applicant. (As seen above applicant elected the species of fluorescein, as set forth in claim 18.) Accordingly, claim 33 is withdrawn from consideration for being drawn to an invention non-elected by applicant.

9. The requirement is still deemed proper and is therefore made **FINAL**.

Claim Objections

10. Claims 1, 2, 6, 12-14, 17, 27, 28 and 32 are objected to because of the following informalities: Said claims encompass non-elected embodiments. Appropriate correction is required.

Drawings

11. The specification as originally filed has been found to contain reference to color drawings, and an Artifact folder has also been located wherein applicant has provided color drawings. However, color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

12. Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Specification

13. The specification has been found to contain numerous trademarks. See, for example, pages 18, 24, and 25 of the specification. They should be capitalized wherever they appear and be accompanied by their respective generic terminology.

14. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1, 2, 6, 9, 12-15, 17-18, 21,22, 27, 28, and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Said claims are indefinite with respect to jut what constitutes the metes and bounds of "polynucleotide binding protein." A review of the disclosure finds a definition at page 23, lines 15-20, however, said definition is non-limiting. Accordingly, the metes and bounds of the claims cannot be readily determined.

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

20. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see

> *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary,

The quantity of experimentation needed is vast, on the order of several man-years, with little if any reasonable expectation of success.

The amount of direction or guidance presented,

The amount of guidance provided is extremely limited, leaving the fundamental issues of full enablement to the pubic to resolve.

The presence or absence of working examples,

Pages 29-32 of the specification have been found to provide seven examples. Of these seven examples, none have been found to set forth specific reaction conditions whereby any target RNA can be detected. The examples do suggest that a Tat-C probe as well as a SH3-C peptide

can bind to a target sequence. The specification, however, does not set forth reproducible conditions under which the polynucleotide binding protein is synthesized and used. Further, the specification does not set forth reproducible conditions under which the elected fluorescent dye is produced and used in combination with the elected species of nucleic acid- single stranded RNA.

Acknowledgement is made of Example 4, and that RNA is bound by Tat-C* probe. It is further noted that specification at page 29 states:

> The polypeptides modified by fluorescein on the N- terminus (Tat-C* and SH3-C*) were custom-made by Sigma-Genosys (Texas, USA).

A review of the specification fails to identify how these "custom-made" probes were in fact prepared. Further, a review of the specification fails to show that these "custom-made" probes were commercially available at the time of filing. Absent such essential starting materials, one is left to conduct routine, trial-and-error experimentation for the development of even a single probe, much less probes that would allow for the binding of any RNA of interest.

The specification also teaches that TAR RNA was secured through a commercial source. The specification does not teach that the RNA oligonucleotide has any specific, credible, and substantial utility.

The nature of the invention & the predictability or of the art

The claimed method relates to the detection of nucleic acids through the use of non-specific binding members where a fluorescent signal is to be detected. As noted above, the method employs non-specific binding of nucleic acids. At best, the method would be able to allow for the detection of nucleic acids in general, yet there is no limitation that ties the binding of the

polynucleotide binding protein to any level of specificity. It is not enough that the claimed method result in some product. In order to satisfy the requirement of enablement, it is imperative that the claimed method result in a product that satisfies the utility requirement under 35 USC 101, and do so in a predictable manner and that said method be disclosed in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains. The claimed method is not so limited.

The claimed method requires one to use a "polynucleotide binding protein." As noted above, the tern has been deemed to be indefinite. The specification has not been found to set forth any example, real or prophetic, or any other description whereby any specific polynucleotide binding protein will result in the identification of useful RNA in a predictable manner. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The breadth of the claims.

The claims fairly encompass the detection of any and all manner of nucleic acids. While applicant has elected the species of single stranded RNA, there is nothing that would preclude the same binding and signaling moieties from binding non-target molecules, and thereby result in false positive signals. Further, the specification is silent as to how a skilled artisan would differentiate between signals that arose from a non-target as well as target nucleic acids.

For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

21. At page 9 of the response of 26 November 2007, hereinafter the response, applicant's representative asserts that the claims encompass the use of a "polycationic multichromophore." This argument has not been found persuasive as such a limitation was presently in newly added claim 33, which has been withdrawn from consideration as being drawn to a non-elected invention. Specifically, applicant, in their response of 18 September 2006 elected the fluorescein as the label. Accordingly, the claims have been examined to the extent that they read on the elected species. And in the instance of new claims being added, and which read on non-elected species/inventions, said claims have been withdrawn from consideration.

22. Applicant's representative, at page 9, last paragraph, of the response asserts that "one of skill in the art is capable of performing control experiments."

23. The above argument has not been found persuasive towards the withdrawal of the rejection as the claims do not require any "control experiment" be conducted. Further, there is no showing as to how such a control experiment is to be performed. Indeed, the specification has not been found to set forth reproducible conditions, real or prophetic, that teaches a reproducible method whereby any meaningful result is obtained by the binding of any polynucleotide binding protein to any RNA of interest.

24. To the extent that applicant's representative has made assertions as to what the level of skill is, and/or what one of skill in the art would be capable of doing, attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

25. At page 10 of the response argument is presented that "The examples demonstrate the ability of the invention to provide a method of detecting a target polynucleotide in a sample using a sensor polynucleotide-binding protein. Nothing more is required by the claims."
The above argument has been fully considered and has not been found persuasive. As noted above, the elected invention is drawn to the binding of single-stranded RNA by a polynucleotide binding protein, and its detection is fluorescein. None of the examples teach such a method. Attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

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> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

26. At page 10, fifth paragraph, argument is presented that "if Applicants wish to use a sensor PBP that can bind to multiple target polynucleotides, that is within the scope of the invention."

27. The above argument has not been found to be persuasive towards the withdrawal of the rejection as the product, be it a single molecule of single-stranded RNA or several different single-stranded RNAs, the end result must satisfy the utility requirement. To put it another way, one cannot satisfy the enablement requirement by arguing that a method can produce a product that has no utility.

28. At page 10, penultimate paragraph, argument is presented that the rejection cannot be maintained "as al of the Wands factors were not analyzed." This argument has not been found persuasive towards the withdrawal of the rejection as it is not a requirement that al of the factors be addressed.

29. At page 11 of the response argument is presented that no factual reason has been set forth that relates to the predictability of the art, and that the decision in *Fisher* is not relevant.

30. The above argument has been fully considered and has not been found persuasive for as noted above, the method employs non-specific binding of nucleic acids. At best, the method

would be able to allow for the detection of nucleic acids in general, yet there is no limitation that ties the binding of the polynucleotide binding protein to any level of specificity. It is not enough that the claimed method result in some product. In order to satisfy the requirement of enablement, it is imperative that the claimed method result in a product that satisfies the utility requirement under 35 USC 101, and do so in a predictable manner and that said method be disclosed in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains. The claimed method is not so limited.

31. Acknowledgement is made of Example 4, and that RNA is bound by Tat-C* probe. It is further noted that specification at page 29, lines 14-15, of the specification states:

> The polypeptides modified by fluorescein on the N- terminus (Tat-C* and SH3-C*) were custom-made by Sigma-Genosys (Texas, USA).

32. A review of the specification fails to identify how these "custom-made" probes were in fact prepared. Further, a review of the specification fails to show that these "custom-made" probes were commercially available at the time of filing. Absent such essential starting materials, one is left to conduct trial-and-error experimentation for the development of even a single probe, much less probes that would allow for the binding of any RNA of interest. Forcing the public to resort to trial-and-error experimentation for even the most basic of starting materials is not deemed to satisfy the enablement requirement of 35 USC 112, first paragraph.

33. The specification also teaches that TAR RNA was secured through a commercial source. The specification does not teach that the RNA oligonucleotide has any specific, credible, and substantial utility.

34. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

" '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

*****

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

"It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

35. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

36. Claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28, and 30-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

37. The method of said claims is to result in the detection of light emitted by fluorescein (a signaling chromophore). The method is note required to have any level of specificity, or that the target single-stranded RNA has any specific, substantial, and credible utility. Indeed, the claimed method fairly encompasses the binding of mRNA associated with expressed sequence tags, and for which no known utility exists, assuming *arguendo*, that the polynucleotide binding protein does have specificity for a given RNA molecule.

38. Claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28, and 30-32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner
Art Unit 1634

BLS